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HATCH-WAXMAN AND MEDICAL DEVICES

Brian P. Wallenfelt[†]

I. INTRODUCTION.....	1407
II. MEDICAL DEVICE REGULATION	1409
III. COMPARISON OF DRUG AND DEVICE APPROVAL PROCESSES	1412
A. <i>Similarities Between NDA and PMA Requirements</i>	1412
B. <i>Differences Between NDA and PMA Requirements</i>	1414
IV. OVERVIEW OF THE HATCH-WAXMAN ACT AND ITS APPLICATION TO MEDICAL DEVICES	1416
A. <i>Abbreviated New Drug Application (ANDA) and Paper New Drug Application (Paper NDA)</i>	1416
B. <i>Patent Term Extension</i>	1418
C. <i>Uses Reasonably Related to Regulatory Submissions Are Non-Infringing</i>	1419
V. THERE SHOULD BE AN ABBREVIATED APPROVAL PROCESS FOR CLASS III MEDICAL DEVICES	1420
A. <i>Benefits Applicable to Generic Drugs Would Also Be Applicable to Generic Class III Medical Devices</i>	1420
B. <i>Abbreviated Approval Is Even More Appropriate for Medical Devices Than It Is for Drugs</i>	1421
C. <i>Fairness to the Pioneer</i>	1422
VI. EQUIVALENCY IN CLASS III MEDICAL DEVICES.....	1423
VII. CONCLUSION	1425

I. INTRODUCTION

In 1984, the enactment of the Hatch-Waxman Act¹ greatly simplified the approval process for generic drugs. It created the

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1. Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended in scattered sections of 21 U.S.C. and 35 U.S.C.).

abbreviated new drug application (ANDA) process, which allows a generic drug to seek approval through establishing bioequivalence to a previously approved pioneer drug. The generic drug was thus able to avoid much of the time and expense associated with conducting clinical trials to prove safety and efficacy. This abbreviated approval process can lead to generic drugs entering the market more quickly.

Although the ANDA process created by the Hatch-Waxman Act is certainly not a benefit to manufacturers of pioneer drugs, the Hatch-Waxman Act also included provisions that benefitted the pioneer manufacturers. Generally, these benefits take the form of extended patent rights.

Like drugs, class III medical devices² are also subject to a time-consuming and expensive approval process that attempts to ensure the safety and efficacy of the device. But unlike drugs, an abbreviated approval process is not generally available for medical devices. This article will discuss the similarities between medical devices and drugs, and argue that an abbreviated approval process should be available for class III medical devices.

This article will first provide a brief overview of medical device regulation and specifically the medical device approval process.³ This article will also compare the approval processes for drugs and medical devices.⁴ Next, this article will discuss the Hatch-Waxman Act and its current application to medical devices.⁵ This article will then analyze whether an abbreviated approval process for medical devices would be beneficial.⁶ This article will also suggest a test for determining when such an approval process would be appropriate.⁷ Finally, this article will argue that the similarities between medical

2. Although the world of medical devices is quite expansive, this article will focus on those class III medical devices that are subject to the premarket approval process only. Class III medical devices are those devices “purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health” or that “present[] a potential unreasonable risk of illness or injury.” 21 U.S.C. § 360c(a)(1)(C)(ii)(I)–(II) (2012). Additionally, class III medical devices require the highest levels of controls to ensure safety and effectiveness. *See id.* § 360c(a)(1)(C)(i).

3. *See infra* Part II.

4. *See infra* Part III.

5. *See infra* Part IV.

6. *See infra* Part V.

7. *See infra* Part VI.

devices and drugs outweigh the differences and, accordingly, that there should be an abbreviated review process for medical devices.⁸

II. MEDICAL DEVICE REGULATION

Until 1976, medical devices were regulated by the U.S. Food and Drug Administration (FDA) as drugs. Drugs are “articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and . . . articles (other than food) intended to affect the structure or any function of the body of man or other animals.”⁹ This definition is much broader than the standard usage of the term drug. And, in fact, it had been held to encompass items that are now thought of and regulated as medical devices.¹⁰

In 1976, a separate regulatory structure for medical devices was added to the Food, Drug, and Cosmetics Act (FDCA)¹¹ with the enactment of the Medical Device Amendments of 1976 (MDA).¹² Under the FDCA, a medical device is defined as “an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article,” which is “intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals” or “intended to affect the structure or any function of the

8. See *infra* Part VII.

9. 21 U.S.C. § 321(g)(1)(B)–(C) (2012).

10. For example, the United States Supreme Court held that a laboratory diagnostic—one that never touched nor was even in the same room as the patient—was a drug and therefore was subject to the drug approval process. See *United States v. An Article of Drug . . . Bacto-Unidisk*, 394 U.S. 784, 800 (1969).

11. Food, Drug, and Cosmetics Act, ch. 675, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 331–397).

12. Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539 (codified as amended in scattered sections of 21 U.S.C.). In addition to creating a separate regulatory process for medical devices, the MDA also removed medical devices from the reach of varied and potentially conflicting state regulatory schemes. See *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 315–16 (2008) (noting that several states adopted approval processes in the seventies); see also *id.* at 342 (Ginsburg, J., dissenting) (discussing “potentially conflicting state regulatory regimes”). The MDA addressed this with a broad preemption clause that eliminated most medical device regulatory requirements created by the states. See 21 U.S.C. § 360k(a) (stating that no state “may establish or continue in effect with respect to a device intended for human use any requirement” that is “different from, or in addition to, any requirement” of the MDA and “which relates to the safety or effectiveness of the device”).

body of man or other animals” and, to exclude drugs and foods, “does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.”¹³ This broad definition encompasses everything from the ordinary¹⁴ to the extraordinary.¹⁵ However, this article focuses on class III medical devices.

The medical device regulatory structure includes an approval process for medical devices known as a premarket approval (PMA).¹⁶ Similar to the new drug application (NDA) process that is applicable to drugs, the PMA process is quite time consuming and expensive, requiring, among other things, information on the following: clinical investigations, principles of operation, and manufacturing facilities and controls.¹⁷

The PMA process, however, is not required for all medical devices. Instead, medical devices are classified based on the level of controls required to ensure safety and effectiveness.¹⁸ And only those devices requiring the highest level of controls—class III devices—are subject to the PMA process.¹⁹ Complex, implanted medical devices, such as pacemakers,²⁰ are typically among those classified in class III and subject to the PMA process.

However, only those class III devices that were introduced after the enactment of the MDA require PMA approval.²¹ By default, devices introduced before the MDA do not require a PMA.²² The FDA may, however, override this default by regulation and require

13. 21 U.S.C. § 321(h).

14. See, e.g., 21 C.F.R. § 872.6855 (2013) (“Manual toothbrush”); *id.* § 872.6865 (“Powered toothbrush”); *id.* § 886.5850 (“Sunglasses”).

15. See, e.g., *id.* § 880.5740 (“Suction snakebite kit”).

16. 21 U.S.C. § 360e.

17. See *id.* § 360e(c)(1)(A)–(C); see also *infra* Part III.

18. See *id.* § 360c(a)–(d).

19. *Id.* § 360e(a). In addition, class III devices are “purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health” or “presents a potential unreasonable risk of illness or injury.” *Id.* § 360c(a)(1)(C)(ii)(I)–(II).

20. 21 C.F.R. § 870.3610; see also, e.g., *id.* § 872.3630 (“Endosseous dental implant abutment”); *id.* § 872.4760 (“Bone plate”).

21. See 21 U.S.C. § 360c(f) (classifying devices introduced after enactment of MDA as class III); *id.* § 360e(a)(2) (requiring PMA for devices that are class III devices because of § 360c(f)).

22. See *id.* § 360e(a).

a PMA for even a pre-1976 device.²³ In addition, to prevent pre-1976 devices from having a monopoly, a new device that is substantially equivalent to a pre-1976 device is also not subject to the PMA process.²⁴

Those substantially equivalent devices are typically subject to the less rigorous premarket notification process, which is also known as the 510(k) process.²⁵ Under the 510(k) process, a manufacturer notifies the FDA that it intends to introduce a new device, asserts that it is substantially equivalent to a pre-1976 device, and waits for an order from the FDA clearing the device.²⁶

Devices that enter the market through the 510(k) process often do so by establishing a substantial equivalence chain. The manufacturers of new devices assert substantial equivalence to a recently introduced device, the manufacturers of which had previously asserted substantial equivalence to a slightly older device, and so on until the chain reaches a device introduced prior to 1976. Each link in the chain can introduce incremental changes. The devices at the opposite ends of the chains may not have much in common at all.²⁷ Nonetheless, much like the ANDA process available for generic drugs, the 510(k) process provides many benefits. For example, it fosters competition by allowing competitors to enter the market more quickly. But the 510(k) process is only available if the new device can be traced to a pre-1976 device for which the FDA has not required a PMA.

In contrast, there are few shortcuts for competitors wishing to enter the market for a class III device introduced after 1976.²⁸ Competitors typically may enter the market only after successfully completing the rigorous, time-consuming, and expensive PMA process. The PMA process often creates a barrier to entry that allows the pioneer to reap monopoly profits, much like the holder of a patent. Accordingly, competition may be stifled when it comes

23. See *id.* § 360e(b).

24. *Id.* § 360c(f).

25. *Id.* § 360(k). Section 360(k) corresponds to section 510(k) of the FDCA.

26. *Id.*; *id.* § 360(n).

27. This author has previously compared this to the children's game of telephone. See Brian P. Wallenfelt, *Foreword: Is It Time for an Abbreviated Premarket Approval for Medical Devices?*, 39 WM. MITCHELL L. REV. 1026, 1028–29 (2013).

28. There actually are two potential shortcuts. First, a manufacturer may petition the FDA to down-classify the device. 21 U.S.C. § 360c(f)(2)–(3). Second, a manufacturer may reference information (e.g., clinical trial data) in a PMA that was approved more than six years earlier. *Id.* § 360j(h)(4).

to devices subject to the PMA process—specifically, those class III devices introduced after 1976.

The Hatch-Waxman Act, among other things, simplified the approval process for generic drugs with the creation of the ANDA process.²⁹ However, because eight years earlier medical devices were separated from the regulatory structure applicable to drugs, that abbreviated approval process did not extend to medical devices.

III. COMPARISON OF DRUG AND DEVICE APPROVAL PROCESSES

Both class III medical devices and new drugs require regulatory approval prior to market introduction. A new drug may not be introduced until an NDA for it has been approved.³⁰ Similarly, most class III medical devices may not be introduced until an application for premarket approval has been approved.³¹ In both cases, the regulatory processes require clinical trials, which are expensive and time consuming.³² There are other similarities as well. Both processes, at their core, aim to determine whether the product is safe and effective.

A. *Similarities Between NDA and PMA Requirements*

An NDA must include “full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use.”³³ Similarly, a PMA must include “full reports of all information, published or known to or which should reasonably be known to the applicant, concerning investigations which have been made to show whether or not such device is safe and effective.”³⁴ Typically, these investigations take the form of clinical trials that are conducted to demonstrate that the drug or device is safe and effective.

29. See *infra* Part IV.A.

30. 21 U.S.C. § 355(a) (“No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application . . . is effective with respect to such drug.”).

31. *Id.* § 360e(a) (“A class III device . . . is required to have . . . an approval under this section of an application for premarket approval . . .”).

32. See, e.g., *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477 (1996) (discussing the “rigorous” PMA process); *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990) (discussing “costly and time-consuming studies” required in an NDA).

33. 21 U.S.C. § 355(b)(1)(A).

34. *Id.* § 360e(c)(1)(A).

Additionally, an NDA must include “a full list of the articles used as components of such drug”³⁵ and “a full statement of the composition of such drug.”³⁶ Similarly, a PMA must include “a full statement of the components, ingredients, and properties and of the principle or principles of operation, of such device.”³⁷ These requirements are very similar. The only difference is that the PMA must include a full statement of the principle of operation of the device. This reflects a difference in the nature of medical devices and drugs. Medical devices are typically designed to use mechanical or electrical components to perform a therapeutic function. This design needs to be explained to understand and evaluate the device. In any case, this information is quite similar and is used to evaluate the safety and efficacy of the drug or device.

An NDA must also include “a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug.”³⁸ Similarly, a PMA also must include “a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device.”³⁹ Again, these requirements are very similar. One difference is that the PMA additionally requires information about installation of the device. This refers to the procedure to implant or use the medical device. This information is not necessary for a drug, because, typically, a drug is not implanted.

Additionally, an NDA must include “such samples of such drug and of the articles used as components thereof as the Secretary may require.”⁴⁰ Likewise, a PMA requires “such samples of such device and of components thereof as the Secretary may reasonably require,”⁴¹ but if submitting samples is “impracticable or unduly burdensome, the requirement of this subparagraph may be met by the submission of complete information concerning the location of one or more such devices readily available for examination and testing.”⁴² These requirements are also essentially the same. The

35. *Id.* § 355(b)(1)(B).

36. *Id.* § 355(b)(1)(C).

37. *Id.* § 360e(c)(1)(B).

38. *Id.* § 355(b)(1)(D).

39. *Id.* § 360e(c)(1)(C).

40. *Id.* § 355(b)(1)(E).

41. *Id.* § 360e(c)(1)(E).

42. *Id.*

differences here recognize that delivering a sample of a device may be much more burdensome than delivering a sample of a drug.

Finally, an NDA must also include “specimens of the labeling proposed to be used for such drug.”⁴³ Similarly, the PMA also must include “specimens of the labeling proposed to be used for such device.”⁴⁴ Labeling is an expansive concept, which covers not only a traditional label, but also much of the information distributed by a manufacturer about an FDA regulated product.⁴⁵ This requirement, which is identical for an NDA and a PMA, gives the FDA the opportunity to ensure the labeling is, among other things, adequate and truthful.

B. Differences Between NDA and PMA Requirements

Although there are many similarities between the NDA and PMA processes, there are also some differences. An NDA requires information that is not required in a PMA. Similarly, a PMA requires information that is not required in an NDA. These differences do not, however, impact the core of either the NDA or PMA regulatory structures.

For example, an NDA must be accompanied by an assessment of the safety and effectiveness of the drug for the claimed indications in pediatric subpopulations.⁴⁶ Similar information is not required with a PMA. However, this requirement is not related to the evaluation of the safety and effectiveness of the drug. Instead, this relatively recent requirement⁴⁷ was added to spur research into pediatric indications for new drugs. Thus, this requirement serves a secondary goal and does not affect the overall approval scheme for new drugs significantly. In fact, in some circumstances, this requirement can even be deferred or waived by the Secretary of

43. *Id.* § 355(b)(1)(F).

44. *Id.* § 360e(c)(1)(F).

45. *Id.* § 321(m) (“The term ‘labeling’ means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.”). Further, the Supreme Court has held that materials that are not on or in a drug package but are instead mailed separately can still accompany the drug and be treated as labeling. *See, e.g., Kordel v. United States*, 335 U.S. 345, 349 (1948).

46. 21 U.S.C. § 355(b)(1)(G); *id.* § 355c(a)(1)–(2).

47. *See* Pediatric Research Equity Act of 2003, Pub. L. No. 108-155, 117 Stat. 1936 (codified as amended in 21 U.S.C. § 355c).

Health and Human Services.⁴⁸ For example, this requirement may be waived when the drug “is not likely to be used in a substantial number of pediatric patients.”⁴⁹

Additionally, an NDA must be submitted with a list of the patent number and expiration date of any patent that claims the drug or a method of using the drug.⁵⁰ However, this provision is not used by the FDA to evaluate the safety and efficacy of the drug. Instead, it is published after the NDA is approved.⁵¹ The information is then used in the generic drug approval process created by the Hatch-Waxman Act. A PMA does not require similar information because there is no generic medical device approval process.

Similarly, a PMA requires elements that are not required in an NDA. For example, a PMA must include references “to any performance standard . . . which would be applicable to any aspect of such device if it were a class II device.”⁵² Additionally, the PMA must include information to show that the device complies with the performance standard or information to justify a deviation from the standard.⁵³ A performance standard is specific to a type of class II device and includes “provisions to provide reasonable assurance of its safe and effective performance.”⁵⁴ For example, a performance standard may include “provisions respecting the construction, components, ingredients, and properties of the device,”⁵⁵ “provisions for the testing . . . of the device,”⁵⁶ and “provisions for the measurement of the performance characteristics of the device.”⁵⁷ An NDA is not required to submit similar information, because there are no analogous concepts to classes and performance standards for drugs.

As explained, there are many similarities between the information required in a PMA and an NDA. Although there are

48. 21 U.S.C. § 355c(a)(3)–(4).

49. *Id.* § 355c(a)(4)(A)(iii)(II). This may be the case with a drug targeted to a condition primarily associated with adulthood or aging (e.g., erectile dysfunction, Alzheimer’s disease, or osteoporosis).

50. *Id.* § 355(b).

51. *Id.*

52. *Id.* § 360e(c)(1)(D).

53. *Id.*

54. *Id.* § 360d(a)(2)(A).

55. *Id.* § 360d(a)(2)(B)(i).

56. *Id.* § 360d(a)(2)(B)(ii).

57. *Id.* § 360d(a)(2)(B)(iii).

also some differences, the differences are often unrelated to the safety and efficacy determination that is central to both approval processes. Based on the comparison between the drug and device approval processes described above, the abbreviated approval process of Hatch-Waxman could readily be extended to devices.

IV. OVERVIEW OF THE HATCH-WAXMAN ACT AND ITS APPLICATION TO MEDICAL DEVICES

Three provisions of the Hatch-Waxman Act are particularly relevant to medical devices and will be discussed in greater detail below. The first provision discussed is not applicable to medical devices, while the other two are.

A. *Abbreviated New Drug Application (ANDA) and Paper New Drug Application (Paper NDA)*

The Hatch-Waxman Act created a bargain of sorts. It created the ANDA process that focuses on similarity to an already approved “pioneer” drug. It also created an exclusive period following the approval of a new drug during which an ANDA cannot be approved. This exclusive period serves to reward the manufacturer for bearing the heavy burden of completing the new drug regulatory process. But after that exclusive period expires, competitors (i.e., generic drug manufacturers) may enter the market through the ANDA process without going through the time and expense of completing an NDA. This process aims to reward innovation while also spurring competition.

Section 101 of the Hatch-Waxman Act created the ANDA process and the paper NDA process.⁵⁸ Both of these processes create paths to approval of a drug that do not necessarily require conducting clinical trials to establish safety and effectiveness, as would be required for an NDA. These processes can allow a generic drug manufacturer to avoid significant time and expense.⁵⁹

Instead of including “full reports of investigations which have been made to show whether or not such drug is safe for use and

58. Hatch Waxman Act § 101, 21 U.S.C. § 355(b)(1), (j).

59. See, e.g., *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990) (stating that ANDAs and Paper NDAs “permit an applicant seeking approval of a generic drug to avoid the costly and time-consuming studies required for a pioneer drug”).

whether such drug is effective in use,”⁶⁰ an ANDA must show that it is bioequivalent to an already approved pioneer drug.⁶¹ The ANDA must identify the pioneer drug, and the labeling for the generic drug must not prescribe, recommend, or suggest conditions of use that are not approved for the pioneer drug.⁶²

The pioneer’s efforts to develop and get the pioneer drug approved are protected in two ways. First, the Hatch-Waxman Act prohibits approving an ANDA until after a specific time period has passed since the pioneer drug was approved.⁶³ In this manner, the pioneer drug receives a benefit for completing the NDA process. The duration of the exclusivity period corresponds roughly to the degree of novelty of the pioneer drug. For example, new uses of known compounds receive a shorter exclusivity period than entirely new compounds.⁶⁴

Second, an ANDA cannot be approved if doing so would infringe the patent rights of the pioneer drug. The ANDA must include “a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the [pioneer] drug . . . or which claims a use for such [pioneer] drug for which the applicant is seeking approval” that addresses the patent owner’s rights.⁶⁵ This certification may address the patent owner’s rights in multiple ways. For example, the generic drug may certify that there are no patents that cover the pioneer drug, or that all patents that cover the pioneer drug have expired.⁶⁶ Alternatively, the ANDA applicant may file the application but choose to wait until the patents that cover the pioneer drug expire to receive approval.⁶⁷ Lastly, the ANDA applicant may assert that the patents covering the pioneer drug are invalid or would not be infringed.⁶⁸ Filing this assertion is an act of infringement and almost always leads to litigation.

The Hatch-Waxman Act also created a paper NDA process.⁶⁹ It provides many similar benefits to the ANDA process in that it can

60. 21 U.S.C. § 355(b)(1)(A).

61. *See id.* § 355(j)(2)(A).

62. *Id.* § 355(j)(2)(A)(i).

63. *Id.* § 355(j)(5)(F).

64. *Compare id.* § 355(j)(5)(F)(ii), *with id.* § 355(j)(5)(F)(iii).

65. *Id.* § 355(j)(2)(A)(vii).

66. *Id.* § 355(j)(2)(A)(vii)(I)–(II).

67. *Id.* § 355(j)(2)(A)(vii)(III).

68. *Id.* § 355(j)(2)(A)(vii)(IV).

69. *Id.* § 355(b)(2).

be used to avoid conducting new clinical trials. However, unlike the ANDA process, a paper NDA is not about proving bioequivalence.⁷⁰ Instead, in a paper NDA, the applicant still proves safety and efficacy, but does so using studies and data that were gathered by someone other than the applicant.⁷¹

B. Patent Term Extension

The Hatch-Waxman Act also amended the patent law to extend a patent term due to delays in entering the market as a result of the regulatory approval process.⁷² Typically, a patent application claiming a drug will be filed well before the drug is approved by the FDA. The patent term then lasts for twenty years from the date the patent is filed.⁷³ This means that a portion of the patent term will pass before the product may be legally marketed.⁷⁴ Because the regulatory approval process often takes a long time, the effect can be significant. The Hatch-Waxman Act attempted to remedy this by providing a patent term extension to offset, at least in part, the delays associated with seeking regulatory approval under certain circumstances.⁷⁵

70. Compare *id.* § 355(b)(2), with *id.* § 355(j)(2)(A).

71. *Id.* § 355(b)(2).

72. Hatch-Waxman Act, Pub. L. No. 98-417, § 201, 98 Stat. 1585, 1598-1603 (1984) (codified as amended at 35 U.S.C. § 156 (2006)).

73. 35 U.S.C. § 154(a)(2). Although the term of a patent was calculated differently at the time the Hatch-Waxman Act was enacted, the effect was largely the same. For patents filed prior to 1995, the patent term was measured from the date of issuance and lasted for seventeen years. See Patent Act of 1952, ch. 950, 66 Stat. 792, 804 (codified as amended at 35 U.S.C. § 154). Section 154 was amended to provide a twenty-year patent term from the original date of filing by The Uruguay Round Agreements Act, Pub. L. No. 103-465, § 101, 108 Stat. 4809, 4815-16 (1994). In any case, the effect was the same, a portion of the exclusive patent right often passed before the inventor was able to market and commercially exploit the product.

74. *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 669-70 (1990) ("When an inventor makes a potentially useful discovery, he ordinarily protects it by applying for a patent at once. Thus, if the discovery relates to a product that cannot be marketed without substantial testing and regulatory approval, the 'clock' on his patent term will be running even though he is not yet able to derive any profit from the invention.").

75. 35 U.S.C. § 156. There are some limits to the extension though. For example, the term of only one patent may be extended due to the delay associated with the regulatory approval of a single product. *Id.* § 156(c)(4).

Unlike the provisions relating to ANDAs and paper NDAs, this section of the Hatch-Waxman Act expressly references and applies to medical devices.⁷⁶

C. Uses Reasonably Related to Regulatory Submissions Are Non-Infringing

Additionally, the Hatch-Waxman Act amended the Patent Act to carve out a safe harbor from infringement for activities related to regulatory submissions.⁷⁷ As currently amended, this safe harbor states:

It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.⁷⁸

Although this section does not expressly state that it applies to medical devices, the Supreme Court has held that it does.⁷⁹ The Court interpreted “submission of information under a Federal law which regulates the manufacture, use, or sale of drugs”⁸⁰ to apply to the submission of information under *any* provision of the FDCA.⁸¹ The Court additionally reasoned that this safe harbor from infringement for activities related to regulatory submissions serves to offset the patent term extension provided by section 156. If this section did not apply to medical devices, a competitor would need to wait for the patent term and its extension to expire before even beginning to prepare a regulatory submission. This would create a “de facto monopoly” that “would continue for an often substantial period until regulatory approval was obtained” after the patent expired.⁸²

76. *Id.* § 156(f)(1)(B) (“The term ‘product’ means . . . [a]ny medical device . . . subject to regulation under the Federal Food, Drug, and Cosmetic Act.”).

77. Hatch-Waxman Act § 202, 98 Stat. at 1603 (codified as amended at 35 U.S.C. § 271(e)(1)).

78. 35 U.S.C. § 271(e)(1).

79. *See, e.g., Eli Lilly*, 496 U.S. at 661.

80. 35 U.S.C. § 271(e)(1).

81. *See e.g., Eli Lilly*, 496 U.S. at 666.

82. *Id.* at 670.

V. THERE SHOULD BE AN ABBREVIATED APPROVAL PROCESS FOR CLASS III MEDICAL DEVICES

As discussed above, the requirements of a PMA and an NDA are quite similar.⁸³ Additionally, the processes have the same goal: to approve only those products that can establish safety and effectiveness. Yet, the Hatch-Waxman Act created a shortcut for drug approval but not device approval. The ANDA process serves as a shortcut because it allows a new drug to receive regulatory approval through a showing of bioequivalence to an already approved drug. This section will explain why an abbreviated PMA process would be equally beneficial for class III medical devices.

A. *Benefits Applicable to Generic Drugs Would Also Be Applicable to Generic Class III Medical Devices*

Many of the reasons that supported the creation of an abbreviated approval process for drugs are equally applicable to class III medical devices. For example, the ANDA process was created to spur the growth of the generic drug market in the United States and, in turn, create a more competitive market with lower prices for unpatented drugs.⁸⁴ An abbreviated approval process would serve the same goals in the market for unpatented medical devices.

An additional benefit of the abbreviated approval process is that it provides for better allocation of societal resources both by applicants and by the FDA. In general, the resources (money, time, intelligence, etc.) devoted to conducting clinical trials and reviewing results of those clinical trials are not productively deployed when the product in the trial has previously been evaluated. The purpose of a clinical trial is to generate new information (e.g., whether a drug or device is safe and effective). Because a clinical trial conducted on a generic equivalent to an already approved product would be expected to generate the same results as the trial conducted on the pioneer product, the trial will

83. See *supra* Part III.A.

84. *Teva Pharm. USA, Inc. v. Novartis Pharm. Corp.*, 482 F.3d 1330, 1344 (Fed. Cir. 2007) (“A central purpose of the Hatch-Waxman Act is ‘to enable competitors to bring cheaper, generic . . . drugs to market as quickly as possible.’”) (citing 149 Cong. Rec. S15,885 (daily ed. Nov. 25, 2003)); *In re Barr Labs.*, 930 F.2d 72, 76 (D.C. Cir. 1991) (“Congress sought to get generic drugs into the hands of patients at reasonable prices—fast.”).

not generate new information. Accordingly, the trial will not produce any benefit even though conducting and reviewing it will consume significant resources. This reasoning is equally applicable to drugs and medical devices. Assuming equivalency is proven, there is no reason to expect that a clinical trial of a generic medical device would produce new information about the medical device. Accordingly, an abbreviated PMA process would lead to better allocation of resources than would occur if clinical trials were repeated on an equivalent but new medical device.

Although it is always possible that more testing could identify a rare side effect or new issues relating to the safety and efficacy of a device, it is not likely. The clinical trials that are used to approve devices are designed to establish safety and efficacy to a high degree of statistical certainty. More testing is unlikely to alter the conclusions of these tests. And the costs of conducting these tests likely outweigh the possible benefits. In fact, if the opposite were true—that the expected benefits of more testing outweigh the costs—the pioneer should not have been approved in the first place.

Additionally, there are also ethical benefits to an abbreviated approval process for both drugs and devices. Clinical trials generally include a study group and a control group of subjects who are in need of the therapy provided by the drug or the device. The study group receives the therapy (e.g., drug, device, etc.) being evaluated. The control group does not. Often, the control group receives no treatment whatsoever. If a drug or device exists and has been proven to be effective in treating a particular condition, it may be unethical to withhold that treatment from subjects in the control group simply to study an equivalent product. This reasoning is equally applicable to both drugs and devices.

B. Abbreviated Approval Is Even More Appropriate for Medical Devices Than It Is for Drugs

Although there are many similarities between devices and drugs, there are also significant differences. These differences, however, do not support imposing a more robust regulatory process for generic medical devices than exists for generic drugs. If anything, the differences suggest that an abbreviated review process makes more sense for devices than it does for drugs.

For both devices and drugs, an abbreviated approval process is harmful to the pioneer manufacturer. The abbreviated approval

process lowers the cost and time required to for a competitor to enter the market. This of course cuts into the pioneer's sales. However, the typical cost structures for medical devices and drugs suggest that the abbreviated process would be less harmful to medical device pioneers than it is to drug pioneers.

For example, a generic producer will likely be able to avoid more of the costs associated with providing a drug than a medical device. This is because manufacturing costs are likely to represent a larger portion of the costs associated with a medical device than with a drug. Medical devices are usually assembled from multiple physical components, at least some of which may be custom manufactured for a particular device. These components and the skilled labor required for their assembly may be expensive. Drugs, on the other hand, are less likely to have these expenses.

Instead, the costs of drugs are often attributed to the research and development costs associated with discovering and investigating pharmaceutical compounds.⁸⁵ Of course, medical devices also often have significant research and development costs. And in both cases, the generic producer can avoid these expenses by copying the pioneer.

However, the generic producer cannot avoid the manufacturing costs. And since these may be more significant in devices, the generic manufacturer is comparatively less advantaged with medical devices than with drugs. This difference, if anything, suggests that the manufacturer of a pioneer medical device needs less protection than the manufacturer of a pioneer drug. Accordingly, the process for market entry by a generic medical device manufacturer should not be any more robust than the process for entry by a generic drug manufacturer.

C. *Fairness to the Pioneer*

A potential argument against an abbreviated approval process is that it would be unfair to the pioneer to allow a competitor to enter the market without undertaking the same regulatory expenses as the pioneer. Although a pioneer device manufacturer is treated differently than a generic one under an abbreviated

85. See, e.g., Mathew Herper, *The Cost of Creating a New Drug Now \$5 Billion, Pushing Big Pharma to Change*, FORBES (Aug. 11, 2013), <http://www.forbes.com/sites/matthewherper/2013/08/11/how-the-staggering-cost-of-inventing-new-drugs-is-shaping-the-future-of-medicine/>.

approval process, this is not necessarily unfair when the full context of the Hatch-Waxman Act, including its benefits, are considered. Additionally, creating an abbreviated approval process for medical devices would create fairness across industries in that drug and device manufacturers would be treated equally.

The Hatch-Waxman Act created benefits to pioneer drug manufacturers to offset, at least in part, the potential unfairness of competitors having an easier path to market entry. If anything, the Hatch-Waxman Act currently unfairly benefits pioneer medical device manufacturers because it provides many of the benefits to medical devices without imposing the corresponding detriments. Most significantly, the Hatch-Waxman Act provides for patent term extension due to regulatory approval delays.⁸⁶ As noted previously, this benefit is already available to pioneer medical devices, even though the pioneer medical device manufacturer is not subject to the detriment of competitors having access to an abbreviated approval process.

Additionally, the Hatch-Waxman Act provides other protections for pioneer drug manufacturers that could be extended to medical device manufacturers as well. Under the Hatch-Waxman Act, an ANDA may not be approved until a sufficient period of time has passed since the referenced pioneer drug was approved.⁸⁷ In essence, the pioneer drug receives a period of market exclusivity in exchange for bearing the regulatory approval of the NDA process.⁸⁸ A similar delay before an abbreviated application could be approved would be appropriate for medical devices as well.

VI. EQUIVALENCY IN CLASS III MEDICAL DEVICES

An abbreviated approval process for class III medical devices would need to define the criteria for when a generic medical device is equivalent to a pioneer device and thus eligible to take advantage of the abbreviated process. This section discusses equivalency in the ANDA process for drugs and the 510(K) process for medical

86. See *supra* notes 72–76 and accompanying text.

87. See *supra* note 63–64 and accompanying text.

88. This market exclusivity is not guaranteed. A competitor is always free to seek approval through the normal NDA process. In that case, however, the competitor is likely to incur similar regulatory costs as the pioneer did. Accordingly, this is not unfair to the pioneer.

devices and suggests relevant criteria for determining equivalency in an abbreviated approval process for class III medical devices.

The process for determining equivalence for a class III medical device would have to be different from the process of determining equivalence for a drug. An ANDA must include information to establish bioequivalence.⁸⁹ Generally, a drug is bioequivalent if “the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the” pioneer drug when administered similarly.⁹⁰ This standard would not be applicable to medical devices because medical devices do not typically operate through absorption. However, “[f]or a drug that is not intended to be absorbed into the bloodstream, the Secretary may establish alternative, scientifically valid methods to show bioequivalence if the alternative methods are expected to detect a significant difference between the drug and the listed drug in safety and therapeutic effect.”⁹¹ Conceptually, this standard is as applicable to medical devices as drugs and could be the starting point of an equivalence standard for medical devices.

A relevant standard is already applied to medical devices in the 510(k) process. In the 510(k) process, a device may be approved if it is substantially equivalent to a pre-1976 device.⁹² There are two tests for determining substantial equivalence. First, a device is substantially equivalent if it “has the same technological characteristics as the predicate device.”⁹³ Additionally, a device is substantially equivalent even if it “has different technological characteristics” if information is submitted “that demonstrates that the device is as safe and effective as a legally marketed device” and the device “does not raise different questions of safety and effectiveness than the predicate device.”⁹⁴

The first branch of the substantial equivalence standard would be equally effective as an equivalence standard under an abbreviated PMA process. This standard would not allow for the

89. See 21 U.S.C. § 355(j)(2)(A) (2012).

90. *Id.* § 355(j)(8)(B)(i). In some circumstances, a generic drug can be considered bioequivalent even though the rate of absorption is different, so long as the difference is “intentional, is reflected in its proposed labeling, is not essential to the attainment of effective body drug concentrations on chronic use, and is considered medically insignificant for the drug.” *Id.* § 355(j)(8)(B)(ii).

91. *Id.* § 355(j)(8)(C).

92. *Id.* § 360c(f)(1)(A)(ii).

93. *Id.* § 360c(i)(1)(A)(i).

94. *Id.* § 360c(i)(1)(A)(ii)(I)–(II).

long equivalence chains that are common in 510(k) applications.⁹⁵ Instead, it would require a stricter degree of equivalence.

Additionally, an abbreviated PMA could require that equivalence be established to PMA-approved devices only and not to other devices that were instead approved through the abbreviated process. This too would eliminate equivalence chains by requiring that the equivalence comparison be made to the device that did in fact undergo extensive clinical trials and scrutiny. In light of the higher risk profile of class III devices, this degree of strictness may be warranted. While stricter than the 510(k) process, this standard would still encourage a robust generic device market for PMA-approved class III medical devices.

In some cases, establishing this degree of equivalence may involve testing, including clinical trials. However, the purpose of the testing and trials would be quite different than the clinical trials conducted for a PMA. These tests would be focused on establishing equivalency—not on establishing safety and efficacy. Additionally, this testing may be necessary to establish that the manufacturing processes used by the generic manufacturer are sufficient. Again though, proving this is far different than proving that the device itself is safe and effective.

VII. CONCLUSION

The innovations of the Hatch-Waxman Act should be fully extended to medical devices by creating an abbreviated approval process for class III medical devices that mirrors the ANDA process for drugs. As it currently stands, the regulatory approval process for new class III devices stands as a roadblock to market competition, creating a potential monopoly for pioneer medical device manufacturers that can extend beyond the duration of patents that cover the device. But the costs of regulatory approval processes are not the right tools for creating monopoly rights because the costs incurred to undertake repeated regulatory submissions on identical products are wasted. Instead, the medical device regulatory system should aim to facilitate market entry by competitors when the patent on a medical device expires. This is just what an abbreviated approval process would do.

Drugs have an abbreviated approval process, while class III medical devices do not. There is no reason that these two industries

95. See *supra* note 27 and accompanying text.

that are so important to health care should be regulated so differently. The differences between medical devices and pharmaceuticals do not justify this disparate treatment.

The addition of an abbreviated review process for class III medical devices would also remedy an imbalance in the way the Hatch-Waxman Act is applied to medical devices. Many of the benefits of the Hatch-Waxman Act are currently extended to pioneer medical device manufacturers but the detriments are not. This creates a playing field that may be unfairly slanted in favor of the pioneer medical device manufacturer.

Additionally, extending the Hatch-Waxman Act to class III devices would potentially create a more robust generic market for medical devices. Further, it is unlikely that the abbreviated review process would stifle innovation in the medical device marketplace. It certainly has not done so for drugs.